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Michel Serpelloni

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YOUNG & THOMPSON

209 Madison Street

Suite 500

ALEXANDRIA, VA 22314

EXAMINER

SASAN, ARADHANA

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,038	Applicant(s) SERPELLONI, MICHEL	
	Examiner ARADHANA SASAN	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The remarks and declaration filed on 05/13/09 are acknowledged.
2. Claims 10-30 are included in the prosecution.

Response to Arguments

Rejection of claims under 35 USC § 103(a)

3. Applicant's arguments, see Page 2, filed 05/13/09, with respect to the following rejections under 35 USC § 103(a) have been fully considered but are not persuasive.

- Rejection of claims 10-12, 16-19, 23-26 and 29-30 under 35 U.S.C. 103(a) as being unpatentable over Ono et al. (US 5,080,908) in view of Fouache et al. (US 6,630,586)
- Rejection of claims 10, 13-16, 20, 24, 27-28 and 30 under 35 U.S.C. 103(a) as being unpatentable over Olinger et al. (US 5,204,115) in view of Fouache et al. (US 6,630,586)

Please note that Applicant did not argue the rejection of claims 10, 13-16, 20, 24, 27-28 and 30 under 35 U.S.C. 103(a) as being unpatentable over Olinger et al. (US 5,204,115) in view of Fouache et al. (US 6,630,586). However, in the declaration (filed 05/13/09, by Philippe Lefevre), this rejection is mentioned (on Page 2, point 4). The response to the declaration (with respect to the combination of Olinger and Fouache) is based on the reasoning behind the substitution of the hydrogenated starch hydrolysate of Olinger by the branched maltodextrin of Fouache.

Applicant argues that the proposed combination fails to recognize the surprising and unexpected properties achieved by the claimed branched maltodextrins in a

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granule preparation. Applicant argues that, as filed in the Rule 132 Declaration, the claimed branched maltodextrins provide a superior granulation over a maltodextrin, e.g., as mentioned by Ono. Applicant argues that the declaration shows the surprising and unexpected properties of the claimed branched maltodextrins, which are not recognized by the proposed combination of documents.

This is not persuasive because Ono (the primary reference) teaches a method for preparing granules of a mixture of dextrin, starch and cyanocobalamin (Col. 3, line 56 to Col. 4, line 5) and that maltodextrin can be used in the method (Col. 2, lines 44-47). Therefore, the limitations of a mixture of active substance (starch) and maltodextrin is taught by Ono. The deficiency in Ono is that of the branched maltodextrins (with specific limitations of 1-6 glucoside linkages, reducing sugar content, polymolecularity index and number-average molecular mass). This deficiency is remedied by Fouache who teaches the branched maltodextrins as instantly claimed.

The obviousness rejection is based on the combination of Ono and Fouache. One of ordinary skill in the art would use the method of preparing granules of a mixture of starch and dextrin (taught by Ono). Since Ono discloses that maltodextrin may be used in the process, one of ordinary skill in the art would substitute the dextrin of Ono with the branched maltodextrin of Fouache. One of ordinary skill in the art would do this because simple substitution of one known element for another to obtain predictable results is obvious. Please see MPEP 2141. Fouache teaches that the branched maltodextrins are indigestible, i.e. can be used as a source of dietary fiber (Col. 2, lines 45-49). Moreover, Fouache also teaches the advantage the branched maltodextrins as providing an acariogenic composition comprising (Col. 4, lines 15-19). The branched

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maltodextrins can be used in pharmaceutical products (Col. 4, lines 33-43). One of ordinary skill in the art would substitute the maltodextrin of Ono with the branched maltodextrin of Fouache with a reasonable expectation of success in producing a functional product with the nutritional advantages of including an indigestible dietary fiber and having an acariogenic composition.

Since one of ordinary skill in the art would find it obvious to use the method of preparing granules with a branched maltodextrin in place of the dextrin taught by Ono, and since Ono teaches the desirability of the uniform distribution of the active ingredient (Col. 3, lines 4-9), the combination of references will lead to the expected result of obtaining a homogeneous granular product.

Therefore, the rejections of 11/13/08 are maintained.

Response to Declaration

4. Applicant's declaration filed 05/13/09, by Philippe Lefevre, has been fully considered but is not found persuasive.

The declarant compares a granulation utilizing a branched maltodextrin (BMD) with a granulation using a potato-based maltodextrin representative of a maltodextrin (GLUCIDEX® 1) suggested by Ono. The declarant states that the granulation made with the GLUCIDEX® 1 is not homogeneous in shading (as seen in Figure 1 of the declaration) and in particle size distribution.

Since one of ordinary skill in the art would find it obvious to use the method of preparing granules with a branched maltodextrin in place of the dextrin taught by Ono, and since Ono teaches the desirability of the uniform distribution of the active ingredient

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(Col. 3, lines 4-9), the combination of references will lead to the expected result of obtaining a homogeneous granular product.

The comparison provided by the declarant is therefore, neither surprising nor unexpected. Rather, the combination of Ono and Fouache will lead one of ordinary skill in the art to have a reasonable expectation of success of producing a functional granular, product with homogeneously or uniformly distributed active ingredient.

The declarant states that (i) the branched maltodextrin according to the claimed invention is a very specific maltodextrin and is not equivalent to other maltodextrins and consequently dextrans.

This is not persuasive because Fouache teaches the specific branched maltodextrin as required by instant claims. One of ordinary skill in the art would find it obvious to use this branched maltodextrin in place of the maltodextrin suggested by Ono with a reasonable expectation of success in producing a functional granular product with a homogeneously or uniformly distributed active ingredient because Fouache teaches the use of the branched maltodextrin in pharmaceutical products.

The declarant states that the granulation carried out with BMD provides a granulation with a homogeneous particle size distribution and shading (as seen in Figure 2 of the declaration). The declarant states that (ii) solutions containing the branched maltodextrin according to the present invention are far more viscous than solutions containing other soluble fibers available on the market that are capable of being used as granulation binders. The declarant states that (iii) all maltodextrins are not equivalent in granulation and some maltodextrins do not work in granulation.

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This is not persuasive because the branched maltodextrin (along with its application in pharmaceutical products) is taught by Fouache and was available to one of ordinary skill in the art at the time the invention was made. One of ordinary skill in the art would have found it obvious to try various maltodextrins available on the market in the method of preparing granules with a reasonable expectation of success in producing a functional granulate. The added advantages of the branched maltodextrin (acariogenic, indigestible source of dietary fiber) would provide motivation to one of ordinary skill in the art.

Therefore, the rejections of 11/13/08 are maintained.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 10-12, 16-19, 23-26 and 29-30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ono et al. (US 5,080,908) in view of Fouache et al. (US 6,630,586).

The claimed invention is a method for preparing granules of active substances containing dietary fiber. The method consists of granulating a mixture of active substances and branched maltodextrins having between 15 and 35% of 1-6 glucoside

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linkages, a reducing sugar content of less than 20%, a polymolecularity index of less than 5 and a number-average molecular mass M_n at most equal to 4500g/mol. The branched maltodextrins content is between 3 and 13% by weight of the mixture to be granulated. The active substances are selected from the group consisting of starches, starch derivatives, sugars, strong sweeteners, enzymes, vitamins, and pharmaceutical active principles. The active substances do not include soybean proteins.

Ono teaches vitamin B₁₂-containing granules (Col. 1, lines 4-8). The vitamin B₁₂ composition was prepared by using an adsorbent carrier consisting of starch and dextrin (Col. 2, lines 25-31). Ono teaches that the dextrin is available on hydrolysis of starch and various types of dextrin, including maltodextrin can be used (Col. 2, lines 44-47). Dextrin and starch are mixed together first, vitamin B₁₂ is dissolved in water, the vitamin B₁₂ solution is added to the starch dextrin mixture for a uniform dispersion of vitamin B₁₂, and the mixture can be fluidized in a fluidized-bed equipment and spray dried (Col. 2, line 54 to Col. 3, line 13). The resulting granules can be subjected to size selection (Col. 3, lines 31-32). Example 1 discloses the method of preparing granules of a mixture of starch and dextrin and cyanocobalamin (vitamin B₁₂) (Col. 3, line 56 to Col. 4, line 5).

Ono does not expressly teach branched maltodextrins having between 15 and 35% of 1-6 glucoside linkages, a reducing sugar content of less than 20%, a polymolecularity index of less than 5 and a number-average molecular mass M_n at most 4500g/mol.

Fouache teaches branched maltodextrins with "22 and 35% ... glucosidic linkages 1→6, a content of reducing sugars lower than 20%, a polymolecularity index

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lower than 5 and a number molecular weight M_n at most equal to 4500g/mole" (Col. 2, lines 37-42). An acariogenic composition comprising branched maltodextrins and at least one polyol (chosen from sorbitol, mannitol, xylitol and maltitol) is disclosed (Col. 4, lines 15-19). "The content of glucosidic linkages 1 \rightarrow 6, of between 22 and 35%, gives the branched maltodextrins ... a character of indigestibility, the consequence of which is to reduce their calorific value by preventing their assimilation at the level of the small intestine" (Col. 2, lines 45-49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of preparing granules of a mixture of starch and dextrin and cyanocobalamin (vitamin B₁₂), as taught by Ono, substitute the dextrin with branched maltodextrins, as taught by Fouache, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the maltodextrin taught by Ono (Col. 2, lines 44-47) can be substituted with the branched maltodextrins taught by Fouache (Col. 2, lines 37-42) given the advantage that the branched maltodextrins are indigestible, i.e. can be used as a source of dietary fiber (Col. 2, lines 45-49). Moreover, Fouache also teaches the advantage the branched maltodextrins as providing an acariogenic composition comprising (Col. 4, lines 15-19). One of ordinary skill in the art would substitute the maltodextrin of Ono with the branched maltodextrin of Fouache with a reasonable expectation of success in producing a functional product with the nutritional advantages of including an indigestible dietary fiber and having an acariogenic composition.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 10, 24 and 30, the method for preparing granules and the step of granulating active substances would have been obvious over the method for preparing granules of starch, dextrin and vitamin B₁₂, as taught by Ono (Col. 2, line 54 to Col. 3, line 13 and Col. 3, line 56 to Col. 4, line 5). The step of mixing the active substance with branched maltodextrins would have been obvious over mixing of starch and dextrin with vitamin B₁₂, as taught by Ono (Col. 2, line 54 to Col. 3, line 13 and Col. 3, line 56 to Col. 4, line 5) in view of the branched maltodextrins taught by Fouache (Col. 2, lines 37-42). The content of the branched maltodextrins (between 3 and 13% by weight of the mixture to be granulated) would have been obvious over the 5 to 30 weight percent of dextrin on a total amount of vitamin B₁₂, dextrin and starch, as taught by Ono (Col. 2, lines 56-57). The limitation of the active substance would have been obvious over the vitamin B₁₂, dextrin and starch, as taught by Ono (Col. 2, lines 56-57). The active substance is not a soybean protein and instant claims do not exclude the presence of vitamin B₁₂, dextrin and starch. The limitation of the powdered mixture of claim 24 would have been obvious over the powdered starch, dextrin and vitamin B₁₂ taught by Ono (Col. 2, lines 56-57).

Regarding instant claims 11-12, 16 and 25-26, the limitations of the active substances selected from starches, starch derivatives (claim 11), dextrans, maltodextrins, branched maltodextrins (claim 12), and vitamins (claim 16) would have been obvious over the vitamin B₁₂, dextrin and starch, as taught by Ono (Col. 2, lines 56-57) in view of the branched maltodextrin taught by Fouache (Col. 2, lines 37-42).

Regarding instant claims 17 and 29, the method steps would have been obvious over the method of preparing granules of a mixture of starch and dextrin and cyanocobalamin (vitamin B₁₂) where the vitamin B₁₂ was dissolved in 4.5 l of pure water, as taught by Ono (Col. 3, line 56 to Col. 4, line 5) in view of the branched maltodextrin taught by Fouache (Col. 2, lines 37-42).

Regarding instant claim 18, the limitation of approximately 5% maltodextrin would have been obvious over the 5 to 30 weight percent of dextrin on a total amount of vitamin B₁₂, dextrin and starch, as taught by Ono (Col. 2, lines 56-57) in view of the branched maltodextrin taught by Fouache (Col. 2, lines 37-42).

Regarding instant claim 19, the limitation of the water that is introduced in a proportion of 10% by weight of the resulting mixture would have been obvious over the 4.5 l of pure water, as taught by Ono (Col. 3, line 56 to Col. 4, line 5).

Regarding instant claim 23, the limitation of the maltodextrins having between 15 and 35% of 1-6 glucoside linkages, a reducing sugar content of less than 20%, a polymolecularity index of less than 5 and a number-average molecular mass Mn at most equal to 4500 g/mol that is used as a granulation binder for active substances would

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have been obvious over the dextrin used in the granule by Ono (Col. 2, lines 25-31) in view of the branched maltodextrin taught by Fouache (Col. 2, lines 37-42).

7. Claims 10, 13-16, 20, 24, 27-28 and 30 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Olinger et al. (US 5,204,115) in view of Fouache et al. (US 6,630,586).

Olinger teaches a method of producing a xylitol granulate that comprises xylitol and a non-cariogenic binder such as a hydrogenated starch hydrolysate (Col. 1, lines 6-21). Intense sweeteners (such as saccharin, acesulfame K, stevioside, and sucralose) can also be incorporated in the xylitol granulate (Col. 6, lines 20-25). The method of producing the xylitol granulate consists of granulating milled xylitol with a non-cariogenic binder (such as hydrogenated starch hydrolysate in the range of about 0.5% to about 5% by weight) and screening the resulting granulate (Col. 6, line 65 to Col. 7, line 8). Example 10 discloses the method of production of a xylitol granulate with a hydrogenated starch hydrolysate (3% by weight) (Col. 11, lines 50-59).

Olinger does not expressly teach branched maltodextrins having between 15 and 35% of 1-6 glucoside linkages, a reducing sugar content of less than 20%, a polymolecularity index of less than 5 and a number-average molecular mass Mn at most 4500g/mol.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of preparing a granulate of xylitol and hydrogenate starch hydrolysate, as taught by Olinger, substitute the hydrogenate starch

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hydrolysate with branched maltodextrins, as taught by Fouache, and produce the instant invention.

One of ordinary skill in the art would have been motivated to substitute the hydrogenate starch hydrolysate with branched maltodextrins because of the advantage that the branched maltodextrins are indigestible, i.e. can be used as a source of dietary fiber (Col. 2, lines 45-49). Moreover, Fouache also teaches the advantage the branched maltodextrins as providing an acariogenic composition comprising (Col. 4, lines 15-19). One of ordinary skill in the art would substitute the hydrogenate starch hydrolysate of Olinger with the branched maltodextrin of Fouache with a reasonable expectation of success in producing a functional product with the nutritional advantages of including an indigestible dietary fiber and having an acariogenic composition.

Regarding instant claims 10, 24 and 30, the method for preparing granules and the step of granulating active substances would have been obvious over the method for preparing the xylitol granulate with a hydrogenated starch hydrolysate, as taught by Olinger (Col. 11, lines 50-59). The step of mixing the active substance with branched maltodextrins would have been obvious over mixing of xylitol with a 50% solution of a hydrogenated starch hydrolysate, as taught by Olinger (Col. 11, lines 50-59) in view of the branched maltodextrins taught by Fouache (Col. 2, lines 37-42). The content of the branched maltodextrins (between 3 and 13% by weight of the mixture to be granulated) would have been obvious over the about 3% by weight of hydrogenated starch hydrolysate taught by Olinger (Col. 11, lines 57-59). The limitation of the active substance would have been obvious over the xylitol granulate with a hydrogenated

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starch hydrolysate, as taught by Olinger (Col. 11, lines 50-59). The active substance is not a soybean protein and instant claims do not exclude the presence of xylitol or hydrogenated starch hydrolysate. The limitation of the powdered mixture of claim 24 would have been obvious over the milled xylitol taught by Olinger (Col. 11, line 53).

Regarding instant claims 13-16, and 27-28, the limitations of the hydrogenated starch hydrolysates (claims 13 and 27), polyols (claims 14-15 and 28), and strong sweeteners (claim 16) would have been obvious over the xylitol, hydrogenated starch hydrolysate (Col. 1, lines 6-21) and intense sweeteners (such as saccharin, acesulfame K, stevioside, and sucralose) (Col. 6, lines 20-25), as taught by Olinger.

Regarding instant claims 20-21, the limitation of preparing a solution of branched maltodextrins at a solids content of between 10 and 50% would have been obvious over the 50% solution of the hydrogenated starch hydrolysate as taught by Olinger (Col. 11, lines 54-57) in view of the branched maltodextrins taught by Fouache (Col. 2, lines 37-42).

Regarding instant claim 22, the limitation of the solution of branched maltodextrins that has a solids content of approximately 5%, by dry weight of the total solids content of the mixture would have been obvious over the about 3% by weight hydrogenated starch hydrolysate as taught by Olinger (Col. 11, lines 57-59) in view of the branched maltodextrins taught by Fouache (Col. 2, lines 37-42).

Regarding instant claim 23, the limitation of the maltodextrins having between 15 and 35% of 1-6 glucoside linkages, a reducing sugar content of less than 20%, a polymolecularity index of less than 5 and a number-average molecular mass M_n at most

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equal to 4500 g/mol that is used as a granulation binder for active substances would have been obvious over the hydrogenated starch hydrolysate used as a granulation binder, as taught by Olinger (Col. 11, lines 57-59), in view of the branched maltodextrin taught by Fouache (Col. 2, lines 37-42).

Conclusion

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615